IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF TIMOTHY BRIAN MCKINNEY, M.D.

Timothy Brian McKinney, M.D. is an experienced urogynecologist who has performed thousands of pelvic and vaginal polypropylene mesh implant surgeries, including those utilizing Ethicon's Gynemesh PS. Dr. McKinney is a pioneer in urogynecology and has educated hundreds of surgeons in these mesh techniques and has, throughout his career, kept abreast of issues in his field by review and study of the relevant literature.

Despite this extensive career, Plaintiffs seek wholesale exclusion of Dr. McKinney's opinions, yet challenge only his opinions on Gynemesh PS's design, and safety and efficacy. In particular, Plaintiffs claim Dr. McKinney's opinions (1) are based only on "personal experience," which they claim has not been "peer reviewed"; (2) are based solely on literature provided to him by counsel; and (3) his opinions conflict with peer-reviewed literature. Plaintiffs' motion should be denied because:

- **Dr. McKinney is qualified to offer expert testimony in this litigation.** Plaintiffs ignore that Dr. McKinney is a pioneer in the field of urogynecology and that, besides his clinical experience, has an exhaustive background in teaching, training, and research in female pelvic medicine and surgery, all of which qualify him to opine on polypropylene mesh.

- **Dr. McKinney's opinions are supported by a reliable methodology.** Dr. McKinney has kept abreast of the relevant medical literature throughout his career and even formed his opinions regarding the safety and efficacy of polypropylene mesh well before this litigation. There is no merit to Plaintiffs' argument that his opinions are based solely on literature provided to him by defense counsel.

- **Dr. McKinney adequately explains why he disagrees with contrary literature.** Dr. McKinney is familiar with the relevant medical literature, including the contrary literature cited by plaintiff. In his testimony, Dr. McKinney directly addresses this literature, clearly articulating why it is not relevant to his opinions. Moreover, the existence of conflicting literature, alone, cannot serve as a basis to exclude an otherwise qualified expert.

Plaintiffs' challenges to Dr. McKinney's design, and safety and efficacy opinions are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

ARGUMENTS AND AUTHORITIES

I. Dr. McKinney's Clinical Experience with Gynemesh PS Qualifies Him to Give Opinions as to this Product's Design, Safety, and Efficacy.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court in particular has made clear that a physician can draw upon his clinical experience and review of relevant literature to give an opinion on the safety and efficacy of polypropylene mesh products. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of polypropylene mesh products).

Dr. McKinney seeks to offer the same kind of opinion here—*i.e.*, that polypropylene mesh products are safe and effective when implanted appropriately. *See* Ex. D to Pls.' Mot. (Dkt.

2001-4), McKinney Report at 15-16. And he bases that opinion on his extensive clinical experience and review of the relevant medical literature over the course of his career. That career includes being a board-certified Fellow of the American College of Obstetricians and Gynecologists and a practicing urogynecologist since 1990. Ex. 1, McKinney Curriculum Vitae at 2-5. Over the course of his 25-year practice, he has performed over 1,000 polypropylene mesh implant surgeries and has used Gynemesh PS since it was released in 2001. Ex. E to Pls.' Mot. (Dkt. 2001-5), McKinney 4/14/16 Dep. Tr. 51:15-24, 110:14-16. In addition to his clinical practice, he has held professorships in Obstetrics and Gynecology since 1992. Ex. 1, McKinney Curriculum Vitae at 3-5.[1]

Despite this extensive clinical experience and background, his opinions here are not premised solely on that experience, but on his review of the medical literature as well. Indeed, he testified:

> Q. What is the objective basis for your opinion it doesn't differentiate much from the non-mesh repair?
>
> A. It's *from readings* as well as my own personal experience.
>
> Q. And when you say "reading," can you be more specific?
>
> A. Some of the past literature, historic literature on that as well as my experience from residency and my personal experiences with dealing with native tissue repairs.

[1] This Court has frequently allowed physicians with comparable—and even less—experience to testify in similar litigations. *See, e.g.*, *Jones v. Bard, Inc.*, No. 2:11-cv-00114, at 1-2, 6-10 (Dkt. 391) (S.D.W. Va. Jan. 6, 2014) (finding Donald Ostergard, M.D. qualified to opine as to polypropylene and product design based on his performance of thousands of pelvic organ prolapse surgeries and 45 years of practice); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 733-34 (S.D.W. Va. 2014) (finding Harry Johnson, M.D. qualified to opine as to mesh degradation based on his experience implanting at least 750 TVT and TVT-O devices and performance of 25 to 30 polypropylene sling revisions).

Ex. E to Pls.' Mot. (Dkt. 2001-5), McKinney 4/14/16 Dep. Tr. 76:23-77:9 (emphasis added); *see also id.* at 51:8-14 (explaining that Dr. McKinney based his opinion that mesh does not shrink on not only personal experience, but also on "numerous communications and educational talks"); *id.* at 110:23-111:8, 111:22-112:2 (clarifying that Dr. McKinney's "personal experience" has been the basis of several educational abstracts and CME conferences); *see generally* Ex. D to Pls.' Mot. (Dkt. 2001-4), McKinney Report (referencing scientific literature throughout his report to support his opinions). Plaintiffs' argument then that Dr. McKinney's testimony should be excluded because it is based solely on "personal experience" is not only baseless, but ignores well-established *Daubert* law that a physician's reliance on his clinical experience and review of the scientific literature qualifies the physician to give opinions on design, and safety and efficacy. *Tyree*, 54 F. Supp. 3d at 585.

Plaintiffs nonetheless take issue with Dr. McKinney's opinions because they have not been published or subjected to peer review. *See* Pls.' Mem. (Dkt. 2002) at 11, 13. But as this Court recognized, observations made by surgeons in their clinical practice are "obviously" not the "type of opinion [that is] subject to testing or peer review." *Mathison v. Boston Scientific Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *29 (S.D.W. Va. May 6, 2015). Consequently, Dr. McKinney's opinions are not inadmissible merely because his opinions have not been published.

Plaintiffs lodge the same criticism as to Dr. McKinney's research. There they claim that because his research has not been published in a peer-reviewed publication, those opinions are inadmissible under *Daubert*. *See* Pls.' Mem. (Dkt. 2002) at 4, 13-14. But "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability." *Daubert*, 509 U.S. at 593-94. Indeed, as this Court has recognized,

publication "is not dispositive." *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *31 (S.D.W. Va. Apr. 28, 2016).

At bottom, Dr. McKinney's opinions are based on more than "personal experience" and require no "publication" to be admissible. Plaintiffs' challenges to this extent therefore fail.

II. Dr. McKinney's Opinions Are Based on an Appropriate Methodology and Should be Admitted.

As stated, it is an acceptable and reliable methodology for a physician to draw upon his clinical experience and review of relevant literature when forming opinions on the design, and safety and efficacy of polypropylene mesh. *Tyree*, 54 F. Supp. 3d at 585; *see also Trevino*, 2016 WL 1718836, at *32; *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *6-7 (S.D.W. Va. Apr. 24, 2015).

Dr. McKinney used this scientifically reliable methodology here. His report contains multiple references to the scientific literature (*see generally* Ex. D to Pls.' Mot. (Dkt. 2001-4), McKinney Report) and, as noted above, he relied on that literature along with his clinical experience in forming his opinions. But, relying on isolated excerpts of Dr. McKinney's deposition testimony and then taking them out of context, Plaintiffs argue that the literature relied upon is that solely provided to him by Ethicon. *See* Pls.' Mem. (Dkt. 2002) at 10-11. Viewed in context and completely, something entirely different emerges. In fact, as Dr. McKinney explained during his deposition, while "[a] lot"—*i.e.*, not all—of the literature he relied on in his report was provided by counsel, he had already come across most of the articles during the course of his clinical practice:

> Q. The articles that are referenced in your expert report and/or in your reliance list, did you obtain those articles—did you obtain the titles of those articles on your own during any research, or were these provided to you by anyone?
>
> A. A lot of them were provided to me from counsel.

> Q. Okay. But did you do your own PubMed research at any point?
>
> A. I did not. However, I have enough articles that my partner from my practice also has some things, but they were pretty much [all mostly] listed in here, repeats.

Ex. E to Pls.' Mot. (Dkt. 2001-5), McKinney 4/14/16 Dep. Tr. 13:11-23; *see also id.* at 22:5-21 (noting that his opinions are also based in part on his own objective clinical outcomes); Ex. D to Pls.' Mot. (Dkt. 2001-4), McKinney Report at 7 (similar).

Further, Dr. McKinney held his opinions—which have not changed—before this litigation:

> Q. Prior to being retained as an expert for Ethicon, did you have an opinion regarding the safety and efficacy of polypropylene mesh when used in pelvic and/or vaginal surgery?
>
> A. I did.
>
> Q. And what were those opinions?
>
> . . .
>
> A. . . . Since I continue to use polypropylene meshes for reconstruction, I felt that they were safe.
>
> . . .
>
> Q. Okay. Since reviewing materials in your role as an expert for Ethicon, has that opinion changed?
>
> A. No.

Ex. E to Pls.' Mot. (Dkt. 2001-5), McKinney 4/14/16 Dep. Tr. 12:4-19. Given this testimony, Plaintiffs' argument that Dr. McKinney's opinions are based only on literature provided to him by counsel is meritless.

Moreover, none of the case law Plaintiffs rely upon to support this argument apply here. Dr. McKinney did not copy and paste articles supplied to him in his report as the expert *In re*

Mirena IUD Products Liability Litigation, No. 13-CV-6586, 2016 WL 890251, at *25-26 (S.D.N.Y. Mar. 8, 2016), did. Instead, Dr. McKinney thoughtfully reviewed dozens of scientific, peer-reviewed articles and provided opinions based not only on that review but also on his decades of clinical experience.

Nor does Dr. McKinney lack clinical experience like the expert excluded in *Mancuso v. Consolidated Edison Co. of New York*, 967 F. Supp. 1437, 1445 (S.D.N.Y. 1997). On the contrary, Dr. McKinney's clinical experience is extensive. *See* Ex. 1, McKinney Curriculum Vitae at 2-5 (tracking urogynecology experience since 1990). And, despite this Court's reluctance to exclude an expert's otherwise reliable opinions merely because they arise during the course of litigation (*see Trevino*, 2016 WL 1718836, at *24), Dr. McKinney's opinions here are not "litigation driven" as were the expert's opinions were in *Prohaska v. Sofamor, S.N.C.*, 138 F. Supp. 2d 422, 437 (W.D.N.Y. 2001). Indeed, Dr. McKinney had formed his opinions on the safety and efficacy of Ethicon's mesh products well before ever being contacted by counsel. Ex. E to Pls.' Mot. (Dkt. 2001-5), McKinney 4/14/16 Dep. Tr. 12:4-14.

And lastly, Plaintiffs' apples-to-oranges comparison between the pathology samples at issue in *Tyree* and the medical literature at issue here—although novel—is inapposite given Dr. McKinney's report and testimony here. At bottom, Dr. McKinney's opinions are based on much more than just the literature provided to him by counsel. Plaintiffs' reliability argument fails.

III. Even if Dr. McKinney's Testimony Conflicts with Peer Reviewed Literature, That Is Not a Basis on which to Exclude His Testimony.

As long as a qualified expert's opinion testimony is based on sufficient facts and the product of reliable methods that would help the trier of fact to understand a fact at issue in the case, the expert's opinions are not excludible even if those opinions disagree with the literature. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 637 & n.19 (S.D.W. Va. 2013). Thus, an expert who

has reviewed, is familiar with, and has based his opinions upon scientific literature may testify as to those opinions, regardless of whether the expert's report references literature that may contradict his opinions. *See, e.g.*, *Mathison*, 2015 WL 2124991, at *6-7, *34 (holding that Stephen Badylak, M.D. could testify based on his "familiar[ity] with the body of literature reviewing the safety and efficacy of surgical mesh generally" and noting that if there are publications that may counter his opinions that he failed to review in preparing his expert report, "the plaintiffs are free to ask him about those . . . on cross-examination"); *Winebarger*, 2015 WL 1887222, at *8 (similar, but holding with respect to Niall Galloway, M.D.). Thus, even if Dr. McKinney's opinions are at odds with the literature, this is no reason to exclude his testimony.

Plaintiffs nevertheless disregard this fundamental principle, as well as this Court's previous rulings, and argue that Dr. McKinney's opinions should be excluded because he failed to take into account medical literature that conflicts with his opinions. Pls.' Mem. (Dkt. 2002) at 14-15. The case law Plaintiffs rely upon, however, is inapposite. Most of the cases Plaintiffs cite pertain to experts who either completely disregarded contradictory literature (*Rimbert v. Eli Lilly & Co.*, No. 06-0874 JCH/LFG, 2009 WL 2208570, at *14 n.19 (D.N.M. July 21, 2009)) or were unable to explain their reasoning for disagreeing with the literature (*Winebarger*, 2015 WL 1887222, at *8-9; *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *12-13 (S.D.W. Va. Sept. 29, 2014)).[2]

None of these deficiencies apply to Dr. McKinney's opinions. Not only was Dr. McKinney aware of the literature Plaintiffs inquired about during his deposition (Ex. E to Pls.' Mot. (Dkt. 2001-5), McKinney 4/14/16 Dep. Tr. 103:1-7 (noting Dr. McKinney's familiarity

[2] The other cases Plaintiffs cite are misquoted; in fact, the quotes Plaintiffs pull from *Tyree* and *Sumner v. Biomet, Inc.*, No. 7:08-CV-98 HL, 2010 WL 4736320 (M.D. Ga. Nov. 16, 2010) appear nowhere in either case and cannot provide the support Plaintiffs claim.

with "a litany of peer-reviewed articles, systematic reviews, meta-analysis and randomized, controlled trials . . . none of which are included in [his] expert report")), but he also did not blindly ignore literature that may conflict with his conclusions. In fact, he refers to potentially conflicting FDA findings in his expert report and was able to articulate why he stands by his opinions even in light of these findings:

> Q. Do you mention in your report that the FDA changed between 2008 and 2011 from [finding] serious complications are rare to serious complications are not rare, with not rare being, in fact, bolded?
>
> A. I didn't specifically mention that. I just mentioned the FDA reports. I believe that with any POP surgery that there are major complications, and that's kind of why I ended up going into this field in particular . . . because in my residency program, statistics were anywhere from 20 to 40% dyspareunia rate afterwards and the shrinkage of the vagina from native tissue repairs that were being done at that time. So they were not reported to the FDA because it was suture techniques. But with having a material and with that being able to be put through the MAUDE database, you get the data. With native tissue there is no compilation, and that's why the FDA is now requesting a 522 to be done.

Id. at 35:14-36:8; *see also* Ex. D to Pls.' Mot. (Dkt. 2001-4), McKinney Report at 7. He was likewise able to explain why any disagreements contained in medical literature not discussed in his report are not germane to his opinions:

> Q. None of these articles are reported upon as a contrary opinion to your stated expert opinion that polyurethane is inert, correct?
>
> A. Well, in th[ese] particular paper[s], I mean, these are explants which by definition are manipulated materials that are out there. These have been pulled out of the body. They've gone through a series of chemicals to try to end up getting rid of all the tissue that's surrounding them to end up looking at them. So there's trauma that can end up being done to that entire mesh material just from the process involved to try to get these out.

Ex. E to Pls.' Mot. (Dkt. 2001-5), McKinney 4/14/16 Dep. Tr. 63:13-24.

At bottom, Dr. McKinney's opinions do not ignore potentially conflicting medical literature. And even if they do, he has sufficiently explained why he disagrees with the conflicting literature. There is no basis to exclude his opinions on reliability grounds.

In sum, all of Plaintiffs' challenges fail. Dr. McKinney is qualified by his experience to render opinions on the design, and safety and efficacy of Gynemesh PS. And he formed those opinions based on that experience and his review of the medical literature.

CONCLUSION

For the foregoing reasons, Ethicon respectfully asks this Court to deny Plaintiffs' motion.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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